MAY 3 0 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

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1. Device Name :	Magnetic Resonance Imaging Accessory
2. Proprietary Name :	Mark 9000 Phased Array Shoulder Coil
3. Classification :	Class II
4. Establishment Registration #:	1529041
5. Manufacture Facility Location:	USA Instruments, Inc., 1515 Danner Drive, Aurora, Ohio 44202, USA Telephone: 330-562-1000; Fax: 330-562-1422.
6. Performance Standard:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
7. Intended Use:	The Mark 9000 Phased Array Shoulder Coil is a receive-only phased array RF coil, used for obtaining diagnostic images of the shoulder and adjacent regions in Magnetic Resonance Imaging systems. The indications for use are the same as for standard MR Imaging. The Mark 9000 Phased Array Coil is designed for use with the Signa 1.5Tesla MRI scanner manufactured by GE Medical Systems, Inc.
8. Device Description :	The Mark 9000 Phased Array Coil consists of three volume RF coil elements in a phased array design. The coil elements and associated circuitry are enclosed to prevent any exposure to the patient or environment. The coil electronics are enclosed in both the rigid housing and the vinyl coated PVC foam. The coil is positioned on the patient's shoulder during imaging.

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9. Safety and Effectiveness:

Mark 9000 Phased Array Shoulder Coil Product Features	Comparison to Predicate or other 510(k) cleared products
Intended Use Shoulder imaging applications	-Similar to the Mark 5000 Shoulder Coil manufactured by USA Instruments Inc. (K893143) -Similar to the Phased Array Shoulder Coil manufactured by Medical Advances Inc. (K945778)
Indications for Use Identical to routine MRI imaging	-Similar to the Mark 5000 Shoulder Coil manufactured by USA Instruments Inc. (K893143) -Similar to the Phased Array Shoulder Coil manufactured by Medical Advances Inc. (K945778)
Coil Enclosure Material Vinyl coated PVC foam TD 277 Polyurethane Plastic PVC Plastic	-Similar to the Magna 5000 Phased Array CTL Spine Coil manufactured by USA Instruments, Inc. (K000002) -Similar to the Mark 5000 Shoulder Coil manufactured by USA Instruments Inc. (K893143)
Coil Design Receive-only phased array design	-Similar to the Mark 5000 Shoulder Coil manufactured by USA Instruments Inc. (K893143)
Decoupling Switching diode decoupling	-Similar to the Mark 5000 Shoulder Coil manufactured by USA Instruments Inc. (K893143)
Prevention of RF Burns Does not transmit RF power; decoupling isolates the coil elements from RF fields during RF transmission; coil elements and circuitry are enclosed in a non-conductive housing.	-Similar to the Mark 5000 Shoulder Coil manufactured by USA Instruments Inc. (K893143) -Similar to the other Outlook Coils manufacture by Picker International (K945827)
Radio Frequency Absorption Coil is a receive only coil and does not transmit RF power; power deposition during imaging is limited by SAR algorithm	-Similar to the Mark 5000 Shoulder Coil manufactured by USA Instruments Inc. (K893143)
Formation of Resonant Loop Decoupling isolates the coil elements from RF fields during RF transmission; length of cable and stiffness does not permit looping	-Similar to the Mark 5000 Shoulder Coil manufactured by USA Instruments Inc. (K893143)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2001

Mr. Rony Thomas
Vice President, Marketing and Programs
USA Instruments, Inc.
1515 Danner Drive
AURORA OH 44202

Re: K010946
Mark 9000 Phased Array Shoulder Coil
Dated: March 14, 2001
Received: March 29, 2001
Regulatory Class: II
21 CFR §892.1000/Procode: 90 MOS

Dear Mr. Thomas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010946

Device Name: Mark 9000 Phased Array Shoulder Coil

Indications for Use: The Mark 9000 Phased Array Shoulder Coil is a receive-only phased array RF coil, used for obtaining diagnostic images of the shoulder and surrounding regions in Magnetic Resonance Imaging systems. The Mark 9000 Phased Array Shoulder Coil is designed for use with the GE Signa 1.5Tesla MRI scanner manufactured by GE Medical Systems, Inc.

Anatomic Regions: Shoulder and surrounding regions.
Nuclei Excited: Hydrogen

The indications for use are the same as for standard imaging:

The GE Signa MRI system is indicated for use as an NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR signal, (2) depend upon NMR parameters (proton density, spin lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010946